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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/792,191	03/03/2004	Chun-Ying Huang	624-040488	4926
7590 04/30/2007 WEBB ZIESENHEIM LOGSDON			EXAMINER	
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700 Koppers Building			. ART UNIT	DARED MEDICE
436 Seventh Avenue			. ARI ONII	PAPER NUMBER
Pittsburgh, PA 15219-1818			1618	
			MAIL DATE	DELIVERY MODE
			04/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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APPLICANT'S INVENTION

Applicant's invention is directed pharmaceutical compositions and methods of 1.

making those compositions.

**Note**: Claims 1-17 are pending.

RESPONSE TO APPLICANT'S ELECTION

2. Applicant's election with traverse of Group I filed 2/14/07 is acknowledged. The

traversal is on the ground(s) that searching the full scope of the claims would not create

an undue burden on the Examiner. In addition, Applicant asserts that the species,

As2O3, As2S3, and As2S2 are not patentable distinct because they all are effective in

the treatment of leukemia. Also, Applicant summarizes various prior art documents as

they relate to the instant invention. This is found non-persuasive because as stated in

the restriction requirement mailed 1/11/07, the compounds may be made by materially

different process. For example, the compounds of the instant invention may be made

by the processes of claims 1 or 6, or by one of the processes disclosed in the prior art

cited below. Furthermore, the claims are product-by-process claims. As a result,

patentability of the claims are not limited to the manipulations of the recited steps when

the prior art discloses the same product as that being claimed by Applicant. Hence, the

restriction requirement is still deemed proper and is therefore made FINAL.

Applicant's election of the species As2O3 and liver tumors is acknowledged in

the response filed 2/14/07.

## WITHDRAWN CLAIMS

3. Claims 6-17 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

## **102 REJECTIONS**

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 5. Claims 1, 2, 4, and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Born et al (Naturwissenschaften, 1941, Vol. 29, pages 182-183).

Born et al disclose mouse experiments wherein radioactive arsenic is utilized. Sodium cacodylate was irradiated with slow neutrons and the radioactive arsenic was separated. The radioactive arsenic was in the form of an aqueous solution of As2O3. The radioactive As2O3 was administered to mice in food or by subcutaneous injection (see entire document, especially, abstract). Therefore both Born et al and Applicant disclose a radiolabeled arsenic-containing compound, As2O3, in combination with a pharmaceutically acceptable carrier. It should be noted that it would be inherent to a skilled practitioner in the art that the radioactive arsenic compound would emit gamma and beta particles because that is one of the properties of radioactive complexes (see Hawley's Condensed Chemical Dictionary, 12<sup>th</sup> edition by Richard Lewis, Sr., page 991

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which defines the term 'radioisotope'. A copy of the dictionary entry is being mailed with this office action).

**Note**: Hawley's Condensed Chemical Dictionary, 12<sup>th</sup> edition by Richard Lewis, Sr., page 991 defines the term 'radioisotope' as an isotopic form of an element (either natural or artificial) that exhibits radioactivity. Radioisotopes are used as diagnostic and therapeutic agents in medicine, biological tracer studies, and for many industrial purposes. Artificial radioisotopes are made by neutron bombardment of stable isotopes in a nuclear reactor.

6. Claims 1- 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Morrison et al (Can. J. Research, 1949, Vol. 27D, pages 265-269).

Morrison et al disclose the distribution of radioactive arsenic in the organs of insect larvae. Radioactive arsenic trioxide (As2O3) containing As76 was injected into larvae. The arsenic solution was prepared by combining active arsenic trioxide with other components including distilled water (see entire document, especially, abstract; page 265, 'Materials and Procedure'; page 266, 'Experimental Procedure', section 2).

Thus, both Applicant and Morrison et al disclose an injectable pharmaceutical composition comprising As2O3 where the 76As isotope is utilized

## **COMMENTS/NOTES**

7. The restriction mailed 1/11/07 was modified. Specifically, Group I should contain only claims 1-5 and Group II should contain claims 6-17. The reason for the change is

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because claims 10-17 depend upon claim 6. Therefore, they should properly be placed in Group II.

- 8. Applicant is respectfully requested to review MPEP 2113, which is directed to product-by-process claims. In particular, Applicant is reminded that even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious form a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process. In other words, product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.
- 9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. L. Jones whose telephone number is (571) 272-0617. The examiner can normally be reached on Mon.-Fri., 6:45 a.m. 3:15 p.m.. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Primary Examiner
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April 23, 2007